

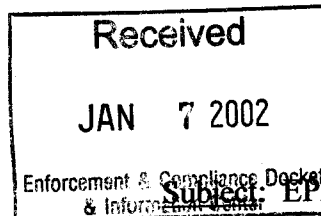
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# Procter & Gamble

The Procter & Gamble Company  
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December 11, 2001

US EPA  
Enforcement & Compliance Docket  
and Information Center  
Mail Code - 2201 A  
Attn: Docket #EC - 2000-007  
1200 Pennsylvania Ave, NW  
Washington, DC 20460



Subject: EPA's Proposed Rule  
to Establish Electronic Reporting;  
Electronic Records (CROMERRR).  
Federal Register: 8/31/01

Dear Sir or Madam,

This presents initial comments on the above referenced proposal from The Procter & Gamble Company and its subsidiaries (P&G), submitted early per EPA request.

P&G develops, manufactures and sells numerous consumer and industrial products directly subject to EPA regulation under TSCA and FIFRA. Substantial recordkeeping and reporting related to TSCA and FIFRA compliance takes place from our technical centers in Cincinnati. In addition, P&G also develops, manufactures and sells a broader range of consumer products including foods, drugs, cosmetics and medical devices subject to FDA jurisdiction. Importantly, "ALL" 37 of our manufacturing plants in 24 states, are subject to extensive EPA and State/local Agency reporting requirements under the CAA, EPCRA, CWA and RCRA. Therefore, this proposal will have significant impact on P&G as well as many many thousands of other large and small companies in the consumer and industrial products industries.

This "early submission" of initial comments from P&G is in response to EPA's specific request that interested persons submit comments "as soon as possible" (Federal Register 11/28/01, Extension of Comment Period, page 59393, bottom Col. 1). We understand EPA is encouraging early submission of comments to provide them information and perspectives to help plan additional public meetings on this proposal to take place during the 60 day extension of time for written comments (11/29/01 to 1/28/02). Since we are continuing to analyze the impact of this proposal on our facilities and systems, including recordkeeping under TSCA and FIFRA, we anticipate submission of additional written comments from P&G before 1/28/02. However, the perspectives and concerns identified thus far will not change, so we will provide them to EPA at this time in an effort to be helpful.

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On August 31, 2001, EPA published in the Federal Register a proposed rule, commonly referred to as CROMERRR—The *Cross-Media Electronic Reporting and Recordkeeping Rule*. This rule states it would “allow” electronic reporting by regulated entities to EPA, and further “allow” these regulated entities to keep EPA-mandated records electronically. Use of the word “allow” creates a false impression. If one did not know better, it might be concluded that electronic reporting and recordkeeping activities were not now permitted nor a common occurrence — which of course they both are. P&G currently uses electronic records to meet most of our environmental recordkeeping obligations. We believe that this is also true for the many thousands of large and small customers and suppliers with whom we do business. The inspectors/regulators who visit our facilities on a routine basis, accept our current records without objection. Records which were created using computers are reviewed either by looking at print-outs or in some cases they are pulled up electronically for regulators/inspectors to view and are printed when requested; and this is accepted. None of our facilities are currently maintaining universally paper-based records systems in support of EPA or any other agency’s regulatory programs. In fact, we project that it would take a large warehouse to store paper documents/records that are now being generated and stored electronically by P&G, in only a year’s time! Yet, if EPA were to promulgate the CROMERRR proposed recordkeeping provisions, it would immediately invalidate most, if not all of our environmental data collection, records and recordkeeping methods. Furthermore, to obtain or design and then implement compliant systems would take many years and many millions of dollars.

The existing, extensive use of electronic recordkeeping and reporting by regulated entities and the new requirements proposed by CROMERRR creates several serious dilemmas: How do you reconcile the - Existing technology - Existing systems - Current electronic reporting - Current recordkeeping practices - Current records - with the new requirements for such records and reports proposed in the rule? Of equal importance and concern is the Agency’s assertion that the proposal is “VOLUNTARY”. It is not conceivable that industry could create or maintain the numerous environmental records required under the various statutes, without the use of computers, given the numerous recordkeeping requirements, all made possible by computer technology. Today, the use of computers for management of our business and for creating and maintaining environmental records is a necessity. Given the existing, overwhelming broadscale use of computers for recordkeeping and reporting in the USA, we do not understand how EPA can assert that CROMERRR recordkeeping provisions are voluntary. Similarly, EPA cannot claim that electronic submittal of data is completely voluntary. Electronic reporting of environmental records is currently “required” under both Federal and state environmental regulation as reviewed in more detail under point #1 in this document (next page).

The preamble also states that this proposal seeks to remove existing regulatory obstacles to electronic reporting and recordkeeping across a broad spectrum of EPA programs, and establish requirements to assure that electronic documents and electronic records are, for all purposes, as valid and authentic as their paper counterparts. The proposal would cover document submissions required by any program governed by EPA’s regulations, except for the Hazardous Waste Manifest, which will be addressed in a separate rule. The proposal also sets forth the conditions under which EPA will “allow” an electronic record to satisfy federal environmental recordkeeping requirements in EPA regulations. Many other complex requirements are also included, along with information on EPA’s electronic document receiving system (CDX); we

will not comment on the CDX receiving system but are, nevertheless, concerned how our electronic submissions will match up with the submission scenarios described in the preamble.

**CONCLUSION:** We have come to the following key conclusions. The Proposed CROMERRR:

- is NOT Voluntary.
- is too complex.
- has HUGE, underestimated adverse economic impact.
- does not identify a cost effective or feasible way to implement the proposed rule's requirements from the base of existing software and hardware that is currently used in the regulated community.
- provides no insight on an implementation timetable.
- appears to presume electronic records are more susceptible to fraud and thus unilaterally imposes elaborate provisions for deterrence.

Because of the burden on industry and states, this rule, if promulgated, would likely have the opposite effect versus its stated intent. Industry and states will do less electronic recordkeeping and reporting than they would otherwise do. Rather than promote use of electronic records and reporting systems, CROMERRR, as proposed, would hinder the use of and development of new electronic record and reporting systems.

**RECOMMENDATION:** We recommend that EPA withdraw its proposal for "recordkeeping" and adopt the practical criteria defined in recent E-SIGN legislation instead of its nine proposed criteria under CROMERRR to qualify a document as valid. Please see Table I. Furthermore, because of the substantive changes that should be made to the entire proposal, EPA should re-propose a revised rule in the Federal Register for subsequent comment.

Each of the above key issues will be discussed in turn in the remainder of this document.

1. First and Foremost : The Rule Is NOT Voluntary - Although the proposed rule presents the reporting and recordkeeping provisions as "voluntary", as written, its requirements would be mandatory for all uses of computers to meet EPA reporting and recordkeeping requirements. This conclusion is based in large part on the rule's definition of electronic record which reads:

"Electronic record means any combination of text, graphics, data, audio, pictorial, or other information represented in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system." (pg. 46189)

Under this definition, any record typed via use of a computer would be subject to the requirements of CROMERRR. Computers are pervasively used in the US for the full range of business communication, recordkeeping and reporting. This will not change.

P&G currently uses electronic records to meet most of our environmental recordkeeping obligations. In most cases, our environmental records are developed using computer technology and are therefore considered to be electronic records (e.g. emission or surrogate emission data from a distributed control system, Continuous Emission Monitor

(CEM) data, computer generated documents and spreadsheets used to calculate and document emissions data, chemical use inventory data taken from electronic materials management systems, etc...). Some environmental logs are created from instrument data which is often averaged over a compliance period and recorded on a computer printout. In some cases sensor data is read and entered manually into a paper or electronic log. Some of our records are maintained only in an electronic form. In any case, virtually all of our many many environmental records use computers in some respect and thus, would be considered electronic records as CROMERRR has defined them in this proposal.

If EPA were to promulgate the CROMERRR's recordkeeping provisions, it would immediately invalidate most, if not all of our current practices associated with environmental records. It would require us either to return to labor intensive data collection methodologies not commonly employed for the last 20 to 30 years or require us to make extensive, almost unimaginable costly and complex changes to our data management systems throughout all of our manufacturing and headquarters facilities. Industry cannot simply turn back the clock and manually collect data. Indeed, the technology advances extensively utilized at manufacturing facilities have allowed regulators to monitor emissions much more extensively than 30 years ago. If computers were not used to collect and store this data, our compliance methods would be far less robust than they are today. We would not have CEMs or surrogate parameter monitoring. We would have far fewer records to collect. For example, without our current computer infrastructure, we might still be measuring air emissions via a single source test once a year vs. using CEMs or surrogate parameters. However, today's compliance requirements which rely on extensive use of computer based information and which monitor emissions or surrogate emissions much more frequently, will continue to be required. Industry simply cannot meet the current environmental monitoring and recordkeeping requirements without extensive use of computers. However, computer systems which exist in the industry and which have been widely accepted as a primary tool for monitoring and recording environmental compliance in the past, have not been designed to meet CROMERRR's massive new requirements.

So, as a practical matter, most if not all entities subject to EPA recordkeeping or reporting rules would have to comply with the CROMERRR requirements. That, in turn, would mean that regulated entities would be forced to adapt their existing computer systems to meet CROMERRR requirements or replace much of its existing hardware and software at a huge cost to all of industry!

On the subject of electronic reporting, EPA cannot claim that electronic submittal of data is not done today. Nor is electronic reporting under CROMERRR completely voluntary. Electronic reporting of environmental records is currently required under both Federal and state rules. Mandated federal electronic reporting directly into an EPA data capture system is required by the Clean Air Act's Acid Rain provisions affecting utilities and under the more recently promulgated NOx SIP and Section 126 Petition regulations for utilities and industrial boilers [40 CFR 75.73 (e) (1) requires electronic reporting of monitoring plans and 40 CFR 75.73 (f) (1) requires electronic submission of quarterly CEM monitoring data]. EPA and numerous states have developed systems and

encourage electronic submission of data for a number of environmental requirements. In most cases, this data is submitted by diskette, which is not considered under CROMERRR to be an electronic submittal. However, in some cases, states have begun to mandate electronic submission of data. Nowhere does the proposal recognize that under state administered programs ELECTRONIC REPORTING is ALREADY REQUIRED. For instance, Louisiana's Tier Two report must be "E-filed" beginning 3/02 [see LAC 33:V.10119 (A)]. Another example of mandatory state reporting of environmental data is Pennsylvania's Continuous Source Monitoring Requirements which require quarterly CEM data reporting directly into a state-developed data capture system, along with diskette and hard copies of the CEM data formatted per PA instructions. [See: PA Chapter 139.101.1. iv., referencing PA's Continuous Source Monitoring Manual Revision 6. Pages 34 – 35 (I. B.1.a.)].

In addition to incorrectly assuming that electronic recordkeeping is voluntary, EPA also incorrectly presumes that electronic reporting is not currently allowed. This could pose major problems for states who have developed systems for voluntary electronic submittals of compliance data. As EPA states in their proposal (pg.46164, Col 1-bottom): "Many facilities do not submit documents directly to EPA, but rather to States, tribes or local governments that are approved, authorized or delegated to administer a federal environmental program on EPA's behalf or to administer a state environmental program in lieu of the federal regulatory program in that State"... "This proposal will allow for EPA approval of changes to authorized State and tribal programs to provide for electronic reporting, and EPA's approval will be based largely on an assessment of the State's or tribe's "electronic document and retrieving system" that will be used to implement the electronic reporting provisions." If CROMERRR reporting requirements are promulgated as proposed, States will suddenly be subject to EPA review and approval of their current electronic reporting/record systems. States will be required to redesign their current systems to meet newly defined (and currently unspecified) requirements for electronic reporting. This will be quite costly to States who have been proactive in establishing existing electronic reporting systems.

2. CROMERRR is very complex and detailed – This is especially true of the requirements for records. There is a need for simplification of these requirements and a viable approach is provided by E-SIGN legislation. **The recently enacted "E-SIGN Act"** [E-SIGN Act = "The Electronic Signatures in Global and National Commerce Act of 2000"; Public Law #106-229] contains criteria which are a feasible and very reasonable alternative to the very costly and technologically demanding requirements EPA has proposed for electronically maintained records in CROMERRR. **The integrity standard** of acceptance for E-SIGN documents is simple: the electronically maintained record must be accurate and accessible.

E-SIGN is very important because it is now broadly utilized to govern electronically created and maintained records. It establishes the legal equivalence between: (1) contracts written on paper and contracts in electronic form (2) pen-and-ink signatures and electronic signatures and (3) other legally-required written documents (termed "records" in the statute) and the same information in electronic form. As a general rule, if parties to

a transaction in interstate commerce choose to use electronic signatures and records, E-SIGN grants legal recognition to those methods. E-SIGN provides that no contract, signature, or record relating to such a transaction shall be denied legal effect *solely* because it is in electronic form, nor may such a document be designed legal effect *solely* because an electronic signature or record was used in its formation. It is also worth noting that the "Government Paperwork Elimination Act (GPEA) of 1998 (Public Law #105-277) provides similar language for government filings covered by this rule and provides similar legal validity for associated electronic signatures.

When E-SIGN took effect October 1, 2000, statutes or agency rules containing paper-based requirements that might otherwise deny effect to electronic signatures and records in consumer, commercial or business transactions between two or more parties were superseded. E-SIGN applies broadly to commercial, consumer, and business transactions in or affecting interstate or foreign commerce, including transactions regulated by both federal and State government. However, the conferees who drafted this legislation specifically excluded "governmental transactions" from the definition of transactions that are subject to E-SIGN. Regrettably, E-SIGN does not cover transactions that are uniquely governmental, such as the transmission of a compliance report to a Federal or State agency. Nonetheless, E-SIGN does cover documents that are created in a commercial, consumer, or business transaction, even if those documents are also submitted to a governmental agency or retained by the regulated community for governmental purposes.

The two E-SIGN document integrity requirements of accurate and accessible are included in the nine requirements EPA proposes for records under CROMERRR. If EPA wants to ensure that certain environmental records cannot be tampered with, or if EPA feels it needs an electronic audit trail, it should identify a rationale and go through a cost/benefit analysis to demonstrate that these additional protections are warranted for specific instances. However, to mandate ALL nine requirements for EVERY electronically created and maintained record is not appropriate or cost effective. It is unclear why EPA should mandate these new requirements which are aimed at simplifying agency enforcement processes, when these features are not required for current records, under a provision which is intended to promote electronic recordkeeping/reporting. As stated previously, these overburdensome recordkeeping requirements will not increase use of electronic reporting/recordkeeping and will not streamline reporting and recordkeeping for industry or states. Instead, these requirements would hinder use of electronic reporting.

Therefore, we recommend that the two logical and practical E-SIGN validity standards, only, be seriously considered and adopted for electronically maintained records under CROMERRR rather than all nine elaborate and complex criteria (which are both costly and raise questions of technical feasibility) that EPA is currently proposing (preamble pg. 46170, Col. 1). **Table I** which is attached contrasts the trustworthiness/validity criteria of CROMERRR and E-SIGN for records.

We must also raise concern over the CROMERRR requirement that electronic data archived must continue to be retrievable in a readable format for years/even decades into the future. This is a big challenge and remains an unresolved compliance issue for FDA under their similar Part 11 requirements. Computer systems and even data formats change, often more frequently than desired. Versions that are replaced or superseded lose their technical support and flexibility to meet all the "latest" requirements.

3. Adverse Cost Impact is Very High – EPA has projected large but substantially underestimated cost impacts on regulated facilities. An important reason the EPA underestimates the cost impact relates to their incorrect assumption that the rule is "somehow" voluntary. The CROMERRR recordkeeping provisions alone would seem to impose very high implementation costs on regulated companies, potentially in the millions of dollars per company, and well in excess of the \$40,000 per facility estimated in the preamble. The Food and Drug Administration promulgated very similar electronic reporting/recordkeeping requirements over 4 years ago, and the pharmaceutical industry has already spent millions of dollars thus far in attempts to retrofit and upgrade their computer software and hardware. This compliance work and associated costs, we might add, is far from complete.

Furthermore, the scope of CROMERRR is vast. It would apply to virtually all organizations subject to Federal environmental laws. The Cost Benefit Analysis prepared for EPA by the Logistics Management Institute (GSA contract GS-35-F-40416) estimates that there are 1.2 million reporting facilities subject to EPA regulations. This same report as well as the preamble to CROMERRR estimates a cost per facility to "start-up" a compliant recordkeeping system alone, at \$40,000. Multiplying these numbers together equals **\$48 Billion**. This is a huge cost. In addition, the same report and also the preamble to CROMERRR estimate yearly maintenance costs per facility to be \$17,000. Multiplying this ongoing cost by the 1.2 million reporting facilities yields the figure of **\$20 Billion** per year ongoing cost (in year 2000 dollars) which will escalate from inflation. This is a huge ongoing cost impact. As has been pointed out by others, \$48 Billion is approximately seven times EPA's annual budget.

The above cost impact numbers are from the contractors report. While we are unable to determine the actual number of reporting facilities or facilities actually impacted, EPA itself, in its Annual Report 2000, states that there are actually 1.7 million entities that maintain compliance data. If this EPA number were used instead of 1.2 million, the cost impact would be revised upward by 40% to \$67 Billion for "start up" and \$28 Billion "on going".

It is unlikely that many people will read the actual 62 page Cost-Benefit Analysis as it was not published as part of the rule, instead being added to the docket record. However, it contains some important information and conclusions that are not included in EPA's preamble to CROMERRR. **Table II**, attached, contains several important excerpts from this report with brief comments by P&G for perspective.

Some key statements contained in the report/along with our comments are:

- a. The primary programs impacted by CROMERRR are: CAA, EPCRA, FIFRA, CWA, RCRA, and TSCA. **Comment:** This represents millions of records and millions of reports.
- b. There are approximately 1.2 million reporting facilities. **Comment:** We conclude this same number of facilities must also keep environmental records.
- c. CROMERRR does mandate minimum features for electronic recordkeeping, electronic reporting, and electronic signature. **Comment:** These “minimum features” are SUBSTANTIAL by any measure and are “add-ons” to existing computer hardware and software or will require wholesale replacement of equipment.
- d. On the basis of these costs, the contractor concludes that very few facilities (0.5%) will make the investment needed for implementing electronic recordkeeping to support compliance reporting under CROMERRR. **Comment:** We understand the report’s conclusion that a very small percentage of the regulated community would volunteer for the electronic recordkeeping provisions of the current proposal. This results from the large costs and unavailability of technology to implement the proposed new requirements. However, the contention that adoption of the electronic form for records or reports is voluntary is wrong given the broad definition of an electronic record and the reality of current pervasive business use of computers for recordkeeping.
- e. Electronic recordkeeping under CROMERRR is expensive and so will proceed slowly until the cost of technology decreases. **Comment:** While the statement is true, given the expensive provisions of CROMERRR, it also provides an alert to the need for a lengthy adoption timetable. However, it does not convey the already pervasive use of computers for recordkeeping and reporting to EPA.
- f. There are large system costs unique to electronic recordkeeping under CROMERRR. **Comment:** We agree. Further, you can’t have electronic “reporting” without records and those records will dominantly use electronic creation and storage. So, the cost for “BOTH” are large; they are not totally separate systems.

It also must not be overlooked that records are necessary to substantiate non reporting. So added to the 1.2 million reporting entities are others who do not report but who must also keep records to verify that they did not meet a reporting threshold that would trigger an actual report. These additional recordkeepers are what has likely been built into EPA’s estimate of 1.7 million entities that maintain compliance data. This adds a half a million more entities subject to the requirements of CROMERRR, since these organizations currently use one or more forms of electronic acquisition, summarization, communication or storage of relevant data/information. Therefore, a more accurate estimate of aggregate cost impact for CROMERRR should derive from using 1.7 million entities impacted rather than only the 1.2 million entities that actually “report”.

CROMERRR also seems to assume one electronic system impacted per reporting facility. However, most facilities will have multiple systems impacted; a large size facility could easily have 20 different systems of varying complexity and cost. Each of these systems would require upgrading, replacement or enhancements to comply with CROMERRR. This is a significant undertaking in terms of manpower and expense including up-front capital costs that would be incurred to modify all impacted systems to meet CROMERRR

standards. If vendor technology does not exist for a compliance requirement, the company may need to write software and thereby incur programming, specifications, coding, and validation activities at significant effort and expense. New software and upgrades will always incur validation and support costs. In the CROMERRR proposal EPA estimated "The average annual cost to implement a new electronic record keeping system is \$40,000 for each facility...". A more realistic estimate would be that each "system" within a facility could easily average \$40,000. Therefore, in a large size facility, upgrading/replacing 20 systems could easily cost \$800,000 for that one facility.

Using EPA numbers provided in the CROMERRR proposal, the cost to P&G would be several million dollars. We believe this figure substantially underestimates the true cost impact on our Company. Similarly large companies in the pharmaceutical industry have projected the cost of \$30 – 50 million per company to attain compliance with FDA Part 11. This range of cost impact is far more likely than the projected impact derived from using EPA numbers in the proposal.

4. Current Computer Hardware & Software – Computers and computer controlled equipment are pervasively used today for communication, data recording and comprehensive recordkeeping, including records storage in normal business work practices in the U.S. Computer hardware and software represent HUGE allocations of capital and have taken years to be acquired and installed in virtually every business. This is certainly true for P&G. This equipment in most instances does not meet CROMERRR requirements, and yet it is inconceivable to abandon its use. Therefore, it is inconceivable and in reality IMPOSSIBLE to revert back to hard copy, paper based systems.

It is important to realize that existing software solutions to make existing computer systems and computer controlled environmental monitoring equipment compliant with CROMERRR proposed requirements are NOT readily available. For perspective, FDA has recently been directing manufacturers to a website for information on possible software solutions to their comparable Part 11 requirements. However, it must be clearly understood that while there are contractors that can be employed to develop customized software solutions or replacement equipment, the mere availability of such "help" does not mean companies can obtain easy or timely correction of deficiencies for their unique computer-based systems. Such new corrective technology is not easily integrated into the wide variety of customized existing systems to make them compliant. Further it is not realistic to think that companies can just "throw out" non-compliant systems, including equipment, and do wholesale replacements. This type of change requires a huge budget.

Again, several serious questions arise. How does EPA reconcile that their proposal is "voluntary" and will be implemented by a small percentage of the regulated community given the broad definition of electronic record in the current proposal and the reality of today's computer utilization in the USA? What happens to these pervasive and expensive legacy systems, often with unique operational features implemented by each company, let alone the millions of existing compliance records now stored using existing

computer equipment which currently would not meet requirements of the proposed rule? CROMERRR does not effectively address these serious matters.

5. Implementation Timetable – Realizing that CROMERRR is only now in the “proposal” stage, the issue of eventual implementation must nevertheless be addressed. There is no projected timing information in the preamble regarding implementation.

The Agency would be well advised to check with the FDA regarding the huge compliance challenge and implementation timeframe for their equivalent rule under 21 CFR Part 11. That rule was final in March, 1997 and made effective in September, 1997. Now, over 4 years later there remains substantial non-compliance in the regulated industry, not because the rule could not be understood, but because the cost and equipment impacts are so overwhelming. The FDA has acknowledged this and has decided to exercise “enforcement discretion” after industry highlighted the significant cost and difficulty of complying with the rule. It is now more generally understood that much time for compliance is needed. Comprehensive compliant systems or fixes are not “out there” on the shelf ready to be plugged in. There is no software “silver bullet” that will take care of all the Part 11 requirements for the numerous existing electronic systems. Therefore, FDA’s compliance approach as stated earlier this year in audio conferences is --- as long as you have a written “compliance plan”, identifying electronic systems that are covered by the regulation, as well, as the changes that need to be implemented and a time frame for accomplishing that, with some evidence of good-faith implementation efforts, then you will not be cited for non-compliance. They permit these “compliance plans” to extend an additional several (3-5) years into the future depending on business size. Recall, the FDA rule has been FINAL now for over four years, so adding another 3-5 years, produces a long implementation timeframe totaling 7-9 years. Nevertheless, despite this dialogue and the FDA’s approach to compliance, it remains a concern that the enormity of the compliance challenge facing firms is not recognized by federal agencies. Added to this is the timing needed by states to modify their systems for receiving reports electronically.

This is strong testimony to the huge implementation challenge created by a rule like CROMERRR and the hard to define yet lengthy implementation timeframe that is needed.

6. Records Integrity/Validity – There is a clear perception conveyed in the preamble of an underlying presumption by EPA that there is a “special problem” with the integrity of information reported or records stored, electronically. There seems to be a concern from EPA about fraudulent records and records being changed without authorization. We are not aware of nor do we permit such practices within P&G. However, if EPA has any such concern about any record or a reporting entity, it has the authority to inspect the facility, audit appropriate records, determine reasons for discrepancies and where appropriate administer penalties.

CROMERRR imposes substantial anti-fraud provisions that most current computer systems do not have, nor are they easy to acquire. These anti-fraud provisions extend far

beyond what is required to meet our current environmental recordkeeping and reporting requirements. The Toxic Substance Control Act (TSCA) makes provision for civil and criminal penalties (TSCA Section 16) for any person who violates a provision of Section 15. Section 15 of the Act discusses that it is unlawful for any person to "fail or refuse to establish or maintain records..." [TSCA Section 15(3) (A)]. In addition, other environmental statutes also impose criminal and civil penalties for violations of anti-fraud provisions. Since anti-fraud provisions of the federal criminal code already exist regarding making false statements to the government or keeping fraudulent records required by the government, the rigorous provisions regarding the integrity and security of electronic records as stipulated by CROMERRR appear to be redundant and thus unnecessary. A more cost-effective approach should be defined to address concerns about the validity of electronic records and their long-term maintenance. As previously recommended, we believe the requirements for validity and trustworthiness of records adopted in E-SIGN legislation are appropriate without modification.

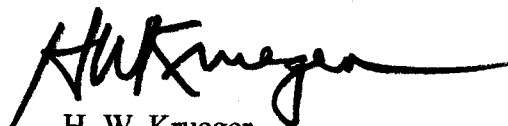
As has been true in the past, there should be the expectation and assumption that reported information and supporting records are accurate. For those records that have been submitted, EPA has the copy of the originally submitted record/report. Its accuracy is not dependent on whether it is in electronic or paper form. If reported information is changed by the reporting entity on their copy, it would not matter whether the archived data was held in electronic or paper form. Therefore, adopting extensive, costly measures for identical application to "every" electronic record and report, in an attempt to establish them as authentic or accurate beyond reproach, or not changed without authorization, is ill advised and unjustified. For other related records for which submission is not required, we recommend adoption of the two E-SIGN validity standards for records of accurate and accessible, only, as presented in the E-SIGN Act. It is also important to note that EPA has a responsibility to institute systems that will not only receive information electronically but maintain its integrity while it is in EPA possession.

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Thank you for your time and attention in considering these comments. As stated earlier, we anticipate submitting additional written comments before the revised comments deadline of 1/28/02.

Table I and Table II attached

Sincerely yours,



H. W. Krueger  
Mgr. Regulatory Affairs - NA  
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**Table I : EPA Requirements for Electronically Maintained Records**

<b><u>CROMERRR</u></b> <b>Nine Criteria EPA is proposing in CROMERRR for Electronically Maintained Records to qualify them as “trustworthy and reliable”</b>	<b><u>E-SIGN*</u></b> <b>Criteria enacted in E-SIGN legislation to qualify a record as trustworthy and valid.</b>
1. The system must generate and maintain accurate and complete copies in a form that does not allow alteration.	1. The record must be accurate.
2. Ensure that records are not altered during a record's retention period.	_____
3. Copies of records are readily available in human readable and electronic form	2. The record must remain accessible to all persons who are entitled to access-----.
4. Any electronic signature contains the name of the signatory, date, time and “meaning” of the signature.	_____
5. The signature on a document cannot be detached, copied or otherwise compromised.	_____
6. Use secure, computer-generated time stamped audit trails for every document to track all changes or deletions, and this record is available for Agency audit.	_____
7. All electronic records are searchable and retrievable for reference, audit or legal proceedings.	_____
8. Archive all electronic records in an electronic form that preserves the context, metadata, and audit trail.	_____
9. Make all computer hardware and software systems available for Agency inspection.	_____

\* E- Sign Act = The Electronic Signatures in Global and National Commerce Act.(6/30/2000)

**SEC. 101. GENERAL RULE OF VALIDITY.**

(a) IN GENERAL. – Notwithstanding any statute, regulation, or other rule of law (other than this title and title II) with respect to any transaction in or affecting interstate or foreign commerce –

- (1) a signature, contract, or other record relating to such transaction may not be denied legal effect, validity, or enforceability solely because it is in electronic form; and
- (2) a contract relating to such transaction may not be denied legal effect, validity, or enforceability solely because an electronic signature or electronic record was used in its formation.

(d) RETENTION OF CONTRACTS AND RECORDS –

- (1) **ACCURACY AND ACCESSIBILITY.** – If a statute, regulation, or other rule of law requires that a contract or other record relating to a transaction in or affecting interstate or foreign commerce be retained, that requirement is met by retaining an electronic record of the information in the contract or other record that -

(A) **accurately** reflects the information set forth in the contract or other record; and

(B) remains **accessible** to all persons who are entitled to access by statute, regulation, or rule of law, in a form that is capable of being accurately reproduced for later reference, whether by transmission, printing or otherwise.

**Table II Cross-Media Electronic Reporting and Records Rule, Cost –Benefit Analysis**  
**(Prepared For the United State Environmental Protection Agency pursuant to GSA Contract**  
**GS-35F-4041G. LOGISTICS MANAGEMENT INSTITUTE, MCLEAN, Virginia 22102-7805)**

Comments of Procter & Gamble on selected portions of this 62-page report		
Page #	Cost-Benefit Analysis – Report Statements	P&G Comments
<u>1-2</u>	<p>“This report describes our economic analysis that compares the current , or “as-is” reporting and record-keeping system with the “to-be” system proposed in CROMERRR.”</p> <p>“In summary, CROMERRR will reduce the paperwork burden for EPA, states, and facilities. EPA estimates that CROMERRR could reduce the average annual reporting cost by \$52.3 million per year for reporting facilities, \$1.6 million per year for EPA, and \$1.24 million for each of the 30 states that we assumed would <u>implement</u> the reporting programs over the 8 years we analyzed.”</p>	<ul style="list-style-type: none"> <li>• We agree, there may be savings opportunities for EPA and the states directly. For facilities that would implement CROMERRR there would be a <u>HUGE UPFRONT INVESTMENT NEEDED</u> by regulated entities.</li> <li>• We agree with the <u>8 years timeframe to implement</u> reporting requirements and record keeping implementation would take no less time!</li> </ul>
<u>3-3</u>	<p>“From the ICR’s and EPA’s Envirofacts database, we have determined that approximately 1.2 million reporting facilities exist, of which approximately 90,000 report directly to EPA. Most of the facilities report for multiple programs either to states or EPA.”</p>	<ul style="list-style-type: none"> <li>• We agree, there are <u>at least</u> 1.2 million* reporting facilities. Worthy of note is that the vast majority report information directly to states (&gt;90%), not to US EPA</li> </ul>
<u>3-7</u>	<p>“CROMERRR does not mandate electronic record keeping . Further, it allows facilities to freely combine paper reporting and record keeping and electronic reporting and record keeping in any way they desire. However, CROMERRR <u>does mandate</u> minimum features that electronic record keeping must support. These requirements stem from the <u>enforcement community</u> to ensure that the electronic data have not been tampered with, reflects the data originally submitted, and “binds” the signer to the data. There also are requirements for providing readable versions for auditors and inspectors, and for ensuring risk of loss caused by intentional or accidental damage to the storage equipment and system is minimal.”</p>	<ul style="list-style-type: none"> <li>• <b>We disagree that CROMERRR is not mandated.</b> It is mandated for those who currently use any computer based system to report information or record data including the associated supporting information (reports, methods, protocols, summaries, data aggregation, etc.). Everybody!</li> <li>• We agree, <b>CROMERRR does mandate minimum features</b> to qualify electronic record keeping. These 9 features disclosed in the preamble are <u>massive new requirements</u> for existing computer software and hardware.</li> <li>• We agree, CROMERRR requirements seem to be for the <u>purpose of “enforcement” alone</u>, since there are no pervasive problems with the trustworthiness of existing computer systems or the validity of electronic records.</li> </ul>

\*From EPA’s Fiscal Year 2000 Annual Report, page II-93- “EPA’s enforcement and compliance assurance program regulates approximately 8 million entities that range from community drinking water systems to pesticide users to major industrial facilities. Compliance data are maintained for approximately 1.7 million of these entities.”

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3-7	Electronic Record Keeping: “Because of the extent and unique nature of these requirements, we assumed for our analysis that, unlike for electronic reporting, most reporting facilities will <i>not</i> have existing automated systems that meet CROMERRR requirements. Our review of commercial systems shows that in the first year, a low-end but scalable system cost approximately \$25,000 plus an estimated additional \$15,000 in internal labor for a training system and process set-up. We estimate annual maintenance of the software and managing the records at \$17,000. <u>These costs are very significant.</u> ”	<ul style="list-style-type: none"> <li>• We agree, the vast majority of reporting facilities will <u>NOT now have automated systems that meet CROMERRR requirements.</u></li> <li>• We agree, the costs for <u>facilities, JUST TO ACQUIRE A COMPLIANT RECORD KEEPING SYSTEM</u>, will be at a minimum \$40,000 each.</li> <li>• Using 1.2 million* reporting facilities per the report (page 3-3), 1.2 MM x \$40, 000 = <b>\$48 Billion</b>, just to “start up” a record keeping system. 1.2 MM x \$17,000 = <b>\$20 Billion</b> yearly maintenance costs. These are <b>HUGE COSTS!</b></li> </ul>
3-8	“On the basis of these costs, we assume that very few facilities (0.5 percent) will make the investment purely for implementing electronic <u>record keeping</u> for compliance reporting. Those that do will likely be in the FIFRA community, which must report extensively to EPA. Another group of mostly large companies <u>have existing electronic document systems</u> for other purposes that could (and likely already do) use them for compliance reporting. We have assigned neither costs nor savings to this group.”	<ul style="list-style-type: none"> <li>• We <u>disagree</u> with the assumption that “very few facilities” will make the investment to implement <u>record keeping</u>--- for compliance reporting. There is linkage between reporting and record keeping – you can’t just separate them – reports require “records”. Existing electronic record keeping supports electronic reporting.</li> <li>• We agree, many companies now use their <u>existing</u> electronic systems for documentation and reporting purposes. This cannot just stop.</li> </ul>
3-8	“Table 3-4 summarizes the as-is and to-be costs for electronic record keeping . Clearly, it is <u>expensive</u> and if it were implemented widely to meet CROMERRR requirements, the burden would increase significantly. For these reasons, we believe implementing electronic record keeping will proceed slowly until the cost of the technology decreases.”	<ul style="list-style-type: none"> <li>• We agree, record keeping costs of CROMERRR are <b><u>prohibitively expensive.</u></b></li> <li>• Conversion technology is NOT readily available and those “new” systems purported to exist are very expensive to acquire. New training would also be needed.</li> </ul>
3-8	“The acquisition of these technologies combined with electronic reporting, are the best means of reducing compliance reporting burden; however, the technologies <u>require a substantial investment cost, and a sophisticated owner or user.</u> ”	<ul style="list-style-type: none"> <li>• We agree, <u>substantial investment is needed at the onset.</u> This is real money that must be “found” in a budget. New technology also requires new training.</li> </ul>

\*As pointed out on page 14: of Table II, EPA states in their Annual Report 2000 that compliance data are maintained by 1.7 MM entities.

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<u>3-9</u>	“Unlike electronic reporting, there are <u>large system costs unique to electronic record keeping</u> . ... In addition, electronic record keeping may put facilities at legal risk. If facilities report electronically but continue to record by paper, they will be conforming to traditional practices in responding to audits, inspections, and enforcement queries and actions. However, inadequately or improperly implementing electronic record keeping creates a risk of being out of compliance.”	<ul style="list-style-type: none"> <li>• We agree, there are <u>large system costs</u> for electronic record keeping!!</li> <li>• We agree, there are compliance risks if you choose to “mix” paper and electronic compliance systems. More importantly, exclusively paper record keeping is neither feasible nor an option in business today.</li> </ul>
<u>5-1</u>	<u>Report Conclusion- Overall:</u> “The United States has become an electronic society. The ensuing years included in this analysis will see an increasing use of electronic tools in all aspects of our lives. Large companies have used EDI for more than 20 years.”	<ul style="list-style-type: none"> <li>• We agree, <u>computers are pervasively embedded in current business practice in the USA</u>.</li> <li>• <b>A Huge investment has already occurred</b> to acquire existing computer equipment which is <u>currently being used for EPA compliance related reporting and record keeping</u>.</li> </ul>
<u>5-1</u>	<u>Report Conclusion- Overall:</u> “However, electronic reporting also creates new issues. One of these is the validity of electronic records in enforcement actions. Many environmental reports require that an authorized person sign them, and the individuals may be penalized for misrepresenting information, failing to report or reporting late, or operating outside of regulated limits. Violators may be subject to enforcement actions.”	<ul style="list-style-type: none"> <li>• Validity of any record is <u>NOT</u> a new issue.</li> <li>• We do <u>NOT</u> assign a greater risk for altering records or misrepresenting information to those documents maintained electronically vs. paper.</li> <li>• EPA has enforcement provisions (inspections, audits, penalties) that can be used now for any falsified record, be it paper or electronic.</li> </ul>
<u>5-1</u>	<u>Report Conclusion- Overall:</u> “Using electronic reporting and record keeping opens questions about how electronic data can be used in enforcement actions. In particular, the question is how data can be linked to a signing official in the same way that a signature of paper can. Electronic records also are vulnerable to being altered either deliberately or accidentally after they have been electronically signed.”	<ul style="list-style-type: none"> <li>• Enforcement actions by Agencies are here to stay. Implementing a costly program like CROMERRR for <b>“every” electronically created compliance document which is maintained/reported is NOT justified</b>.</li> <li>• Altering a record is a decision that is not made easier because that record is held electronically rather than in paper form.</li> </ul>

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5-2	<p><u>Report Conclusion - Facilities:</u>  “Electronic record keeping is less cost-effective. Most small- to medium-size organizations do not have automated electronic record-keeping systems that will meet CROMERRR requirements. Acquiring and implementing even low-end systems is likely to cost \$40,000 or more. <u>This cost is prohibitive</u> for solely preserving environmental compliance reports. However, larger organizations that do have electronic record-keeping systems for other purposes most likely <b>can expand the systems</b> to accommodate electronic compliance reports at little added expense.”</p>	<ul style="list-style-type: none"> <li>• We agree, but even low end systems will cost more than \$40,000 per facility, just to acquire.</li> <li>• We do <u>NOT agree</u> that large organizations will experience “little added expense” to adopt CROMERRR requirements. There are many more software programs to deal with as well as computerized <u>monitoring/lab analysis equipment</u> and an overwhelming amount of associated records.</li> <li>• <u>Changing existing electronic systems</u> is the issue, not just “expanding” them.</li> </ul>
5-3	<p><u>Report Conclusion – States:</u>  “States receive the bulk of compliance reports and represent the front line for generating public trust that organizations are complying with environmental laws and that aggregate trends are being monitored. However, the states often try performing these functions with small budgets and staffs that must use outdated equipment.”</p> <p>“Records processed through electronic reporting will reduce costs for receiving, entering, verifying and storing records. The major difficulty for states probably will be securing the initial investment capital and organizational focus to achieve the return on investment.”</p> <p>“However, the states’ specific implementation approaches for both electronic reporting and electronic signatures may vary from one another’s and from EPA’s.”</p>	<ul style="list-style-type: none"> <li>• Over 90% of compliance reporting is to States. States will <u>not uniformly</u> be prepared to deal with CROMERRR requirements on them. States will move slowly.</li> <li>• Obtaining implementation funds for CROMERRR will take <u>many years</u> for states.</li> <li>• We are concerned about lack of uniformity</li> </ul>
5-4	<p><u>Report Conclusion – EPA:</u>  “Although EPA foresees electronic reporting as a benefit to the agency and other stakeholders, electronic reporting is virtually required by GPEA and other federal initiatives.”</p> <p>“EPA also is in the best position to incorporate electronic record keeping into its operations. However, even for EPA, using GSA’s approach for digital certificates and validation of electronic signatures is expensive.”</p>	<ul style="list-style-type: none"> <li>• EPA benefits from CROMERRR but does not have to come up with the <u>BILLIONS of dollars</u> it takes to implement and maintain the “new systems” necessary for compliance.</li> <li>• We agree, EPA will also have to upgrade existing electronic systems to meet CROMERRR requirements.</li> </ul>

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5-4	<p><b>Report Conclusion – Summary:</b>  “The total average annual costs of implementing and <u>reporting</u> electronically for all facilities is \$3,430 million . . . <b>The average annual cost to implement a new electronic record keeping systems is \$40,000 for each facility...</b>”</p> <p>“Therefore , our estimates indicate that implementing electronic reporting will reduce the net burden for all participants, but for a facilities, developing an electronic records system <u>may not be cost effective unless</u> it addresses both EPA and non-EPA business purposes. However, it will <u>require</u> several years to overcome initial investment for electronic processing, record <u>keeping</u>, and digital certificates and signatures.”</p> <p>“Electronic record keeping will <u>require</u> more research, application of technology, and coordination between enforcement requirements and <u>workable solutions</u> before it becomes cost effective for facilities.”</p>	<ul style="list-style-type: none"> <li>• We agree. This involves <u>HUGE COSTS</u> (with little real benefit) especially for recordkeeping. We also believe these costs to be very conservative.</li> <li>• Implementing the proposed CROMERRR requirements for Electronic Record keeping renders it <u>cost ineffective</u>.</li> <li>• We agree, it would require “YEARS” to overcome initial investment.</li> <li>• We agree, electronic record keeping requires more R&amp;D and coordination to find a workable solution. Therefore, we believe EPA should work with the regulated community and software developers to identify practical requirements BEFORE a CROMERRR-type rule is finalized.</li> </ul>